

REMARKS

I. Claim Rejections Under 35 U.S.C. § 103

In the current Office Action, the Examiner has withdrawn the 35 U.S.C. §102(b) rejection over the Kensey et al. reference (USPN 5,061,274) and now rejects claims 1 and 9 over Ginn et al. (U.S. Pub. No. 2002/0077656) in view of Belhe et al. (U.S. Pub. No. 2004/0215232) as obvious under 35 USC §103(a). The Examiner cites Ginn for teaching all the claim elements except for the bleed back lumen, which includes distal and proximal openings connected by a lumen. As is known in the art, a bleed back lumen facilitates the positioning of intravascular devices since blood will be present at the proximal opening when the distal opening is positioned within the vessel. The Examiner cites Belhe for its teachings regarding an elongate member with a bleed back lumen. The Examiner concludes that it would have been obvious to modify Ginn's device with Belhe's bleed back lumen to "provide visual feedback to the operator as to the location of the device, thus ensuring proper positioning of the occlusion member." Applicant respectfully disagrees with the Examiner's rejection for the following independent reasons.

First, the delivery of the occlusion member as taught by Ginn involves a different approach than represented by the currently pending claims. Specifically, Ginn's device never enters the patient's vessel. Even when advanced to a distal position further than the ideal location, plug member 20 (or 220) is never positioned inside the blood vessel. As described with regard to Figs. 5A and 5B, Ginn describes the use of the device as follows:

Preferably, while advancing the plug member 220, blood flow at a location downstream of the blood vessel 90 is monitored. For example, the patient's pulse may be manually or automatically monitored downstream of the puncture site. The apparatus 210 may be rotated, advancing the plug member 220 until blood flow substantially ceases downstream of the blood vessel. This may indicate that the plug member 220 has engaged and compressed the blood vessel 90, as shown in FIG. 5A.

Rotation of the apparatus 210 may then be reversed to back the plug member 220 a predetermined distance, thereby allowing blood flow to resume downstream of the blood vessel 90. For example, the threads 222 may have a predetermined thread spacing such that the apparatus 210 may be rotated a predetermined number of times to accurately withdraw the plug member 220 from compressing the blood vessel 90 while still substantially sealing the passage 92 at the wall 98 of the vessel 90, as shown in FIG. 5B. Ginn, paragraphs [0039]-[0040].

As clearly indicated, plug member 220 never enters the vessel; at most it compresses the vessel wall at its most distally advanced position. Since the plug member never enters the vessel, the distal end of the elongated delivery member also necessarily does not enter the vessel.

In contrast, both claims 1 and 9 have claim language that clearly requires that the distal end of the elongate member be configured to enter the blood vessel. Thus, Ginn fails to disclose this aspect of the claims. Further, Belhe also fails to disclose the requisite characteristics and relationship of an elongate member and an occlusion member, as the occlusion member (anchor 40) of this disclosure is carried on a separate structure, not elongated member 12 or 14. Accordingly, Applicant respectfully submits that the combination of Ginn and Belhe fails to disclose the invention as claimed and requests that the Examiner withdraw the §103 rejection of claim 1 and 9.

Next, Applicant also respectfully submits that the motivation offered by the Examiner for combining Ginn and Belhe is inappropriate. As quoted above, the Examiner contends that it would be obvious to modify Ginn's device with Belhe's bleed back lumen to facilitate positioning the occlusion member. However, as discussed above, proper function of the bleed back lumen requires advancing the elongate member with the distal opening *into* the patient's vessel, so that blood can perfuse through the lumen and be visible at the proximal opening. Since Ginn's device is explicitly designed so that the occlusion member is not inserted into the vessel, it would be impossible for a bleed back lumen having a distal opening that is proximal to the occlusion member (as the current claims require) to function. Correspondingly, one of skill in the art would have no reason to modify the Ginn device with a bleed back lumen as its elongate member is never intended to have the necessary exposure to the interior of the blood vessel. Without adequate reason to combine the references, Applicant respectfully submits that the Examiner has failed to make a *prima facie* case of obviousness and requests that the §103 rejection of claim 1 and 9 be withdrawn.

Finally, the Examiner has rejected claims 3 and 11 under 35 USC §103(a) as obvious over the combination of Ginn and Belhe discussed above, further in view of Kensey. Applicant submits that Kensey fails to compensate for the deficiencies of the primary combination of Ginn and Belhe. The distinctions between the claimed invention and Kensey have been discussed in previous responses and Applicant submits that the inherent differences between the approach of

the Ginn reference and the invention as claimed in independent claims 1 and 9 remain. Accordingly, Applicant submits that dependent claims 3 and 11 are also necessarily patentable over the art of record and requests that the Examiner withdraw the §103 rejection of these claims.

II. Rejoinder of Claims 5 and 7

As discussed in the previous responses, Applicant continues to request that method Claims 5 and 7 be rejoined when Claim 1 is found patentable, as they have been amended to share all the structural limitations of this product claim.

III. Conclusion

For the reasons set forth above, Applicant submits that the claims are patentable over the cited art. Therefore, applicant requests that the rejections be withdrawn, and that a Notice of Allowance be issued.

Respectfully submitted,

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